9110-9F-P

DEPARTMENT OF HOMELAND SECURITY

Docket No. DHS-2016-0010

Cooperative Research and Development Agreement Opportunity with the Department of Homeland Security for the International Foot-and-Mouth Disease Vaccine and Diagnostics Field Trial

AGENCY: Chemical and Biological Defense Division (CBD), Homeland Security Advanced Research Projects Agency, Science and Technology Directorate, Department of Homeland Security.

ACTION: Notice of intent.

SUMMARY: The Department of Homeland Security (DHS), Science and Technology Directorate (S&T), through its Homeland Security Advanced Research Projects Agency (HSARPA), Chemical Biological Defense Division (CBD) is implementing and executing an international foot-and-mouth disease (FMD) vaccine and diagnostics field trial. The objective of the project is to evaluate a newly developed FMD vaccine(s) and companion diagnostic(s) in an FMDV endemic country. The specific goals of this project are to establish the efficacy of the newly developed replication-deficient adenovirus-vectored FMD (AdFMD) vaccine; the effectiveness, sensitivity, specificity, and ruggedness of a new companion diagnostic test ("3B ELISA") under field conditions, and to provide data on the usage of a DIVA vaccine and companion diagnostic in an endemic disease situation which may be used to inform the U.S. response to an FMD outbreak. DHS anticipates that this project may lead to the

development and fostering of partnerships and collaborations with industry, countries and national and international organizations that will result in a solid foundation that will facilitate the future development and testing of additional transboundary animal disease (TAD) vaccines and diagnostics.

CBD is seeking industry partners to enter into a Cooperative Research and Development Agreement (CRADA). It is envisioned that the primary role of the selected industry collaborator(s) will be to provide subject matter experts to inform the vaccine and diagnostic field trial design(s), country selection and regulatory processes, in addition to potentially developing, manufacturing and distributing or providing, the AdFMD experimental vaccines and companion ELISA diagnostic kits for the field trial.

DATES: Submit comments on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

ADDRESSES: Mail comments and requests to participate to Dr. Roxann Motroni, (ATTN: Roxann Motroni, 245 Murray Lane SW, Washington, DC 20528-0075) Submit electronic comments and other data with the subject line "International FMD Field Trial Notice of Intent" to Roxann.Motroni@hq.dhs.gov.

FOR FURTHER INFORMATION CONTACT:

Information on DHS CRADAs: Scott Pugh, scott.pugh@hq.dhs.gov, (202) 254-2288.

SUPPLEMENTARY INFORMATION:

Background

Ensuring livestock resiliency across the United States is crucial to the economic success of the American livestock industry. Foot-and-mouth disease (FMD) is caused by a highly infectious virus that affects cloven-hoofed animals and causes high morbidity. While the animal health consequences are serious, the economic consequences are grave, since all trade of animals and animal products from the U.S. will cease. Worldwide, FMD eradication and control is difficult as it is costly, requires significant animal health infrastructure, and infection or vaccination with a single strain of a serotype often does not confer protection against other strains of the virus.

Many countries with periodic FMD outbreaks vaccinate with a "killed" vaccine produced by inactivating the FMD virus (FMDV) and adding an immune system stimulant called an adjuvant. The killed vaccine has several drawbacks, including the requirement for high biosecurity production facilities to reduce the risk of accidental release of live FMDV, and the need for costly, sophisticated, and consistent purification procedures to remove FMDV pieces that may cause animals vaccinated with the killed FMD vaccine to test FMD positive in 3B based diagnostic assays.

Because killed FMD vaccines vary in their ability to consistently differentiate infected from vaccinated animals (DIVA), under current regulations, killed FMD vaccine usage in an outbreak could result unnecessarily in the humane euthanasia of both vaccinated and infected animals.

The Department of Homeland Security , and United States Department of Agriculture (USDA) scientists at Plum Island Animal Disease Center, working with industry partners have developed an effective AdFMD vaccine that does not required live FMDV for

manufacturing and is also DIVA compatible, giving the U.S. a key component of implementing a vaccinate-to-live policy. In 2012, DHS S&T successfully pursued licensure for a single FMD serotype, A24 Cruzeiro, however this single vaccine will not protect against the multitude of other FMD serotypes/subtypes/topotypes that exist, thus DHS S&T has interest in continued development of additional serotype and broader spectrum vaccines. Since FMD is not endemic to the U.S., the goals of the International FMD Vaccine and Diagnostic Field Trial are to test the efficacy of these newly developed vaccines, and the DIVA compatibility of the vaccines using one or more companion ELISA diagnostic tests under natural exposure conditions.

Role of the Industry Collaborator

Any selected industry collaborator would play a crucial role in the CRADA partnership to implement and execute the international FMD vaccine field trial. Each proposal must address item 1, and may address one or more of items 2-6:

1. Provide subject matter expertise for vaccine and companion ELISA diagnostic trial design, data analysis, country selection, and import and export regulations for biological products, be they licensed or experimental;
2. Manufacture, test, and release FMD vaccines (experimental AdFMD and/or currently licensed, killed vaccines) and companion ELISA diagnostic kits to be used in field trial;
3. Acquisition, transport, export, and import of the experimental and killed conventional vaccines, and companion ELISA diagnostic kits into the FMD endemic country;

4. Research and development capabilities to construct AdFMD vaccine candidates and/or produce pre-master seed AdFMD viruses for additional FMD serotypes/topotypes/lineages for which new vaccines may be required;
5. Real-time data analysis for the AdFMD field trial as the trial is conducted; and
6. Final data analysis once the international field trial is completed.

Any selected industry collaborator, depending on the terms of the CRADA, would likely benefit by acquiring:

1. Better understanding of FMD epidemiology in the FMD endemic country, which may allow for increased sales and marketing of a company's current inactivated FMD vaccine(s) and FMD ELISA diagnostic kit franchise and;
2. Pre-published knowledge of AdFMD vaccine performance during the field trial, as compared to the current inactivated FMD vaccines;
3. Pre-published knowledge of the ELISA diagnostic performance during the field trial,
4. Understanding of how the AdFMD vaccine may be used with a companion diagnostic test to better plan and execute FMD control and eradication strategies on the local, regional and national levels; and
5. Unique perspectives to better leverage existing public-public partnerships that will focus corporate stewardship toward more cost effective FMD control strategies associated with the United Nations Food and Agriculture Organization (FAO) related to the FMD Progressive Control Programme.

Period of Performance

The CRADA will be in effect for 5 years or 60 months from the effective date of the agreement.

Selection Criteria

DHS S&T reserves the right to not issue a CRADA in response to this announcement or to issue CRADAs to one or more prospective collaborator's proposals submitted in response to this announcement. DHS S&T will provide no funding for reimbursement of proposal development costs. Proposals (or any other material) submitted in response to this notice will not be returned. Proposals submitted are expected to be unclassified. If Proprietary Information is included in proposals, it must be properly marked as such. DHS S&T will select any CRADA collaborator(s) at its sole discretion on the basis of:

1. How well the proposal communicates the collaborators' understanding of and ability to meet the CRADA's goals and proposed timeline.
2. How well the proposal addresses the following criteria as they would be relevant to its proposal:
    a. Availability, qualifications and willingness of subject matter experts to participate in interagency meetings and other teleconferences;
    b. Capability of the collaborator to provide equipment and materials for FMD vaccine and diagnostic manufacturing;
    c. Ability of the collaborator to produce experimental AdFMD vaccine(s) and licensed highly-purified inactivated FMD vaccine(s) for use in the field trial
    d. Ability of the collaborator to produce and provide companion ELISA diagnostic kits for use in the field trial;
    e. Ability of the collaborator to work with appropriate regulatory authorities to allow for export of experimental and licensed FMD vaccines and import of these materials into a partner country;

f. Ability of the collaborator to work with appropriate regulatory authorities to allow for export of companion ELISA diagnostic kits and import of these materials into a partner country.

Participation in this CRADA does not imply nor create any obligation on DHS's part for the future purchase of any materials, equipment, or services from the collaborating entities, and non-Federal CRADA participants will not be excluded from any future DHS S&T procurements based solely on their participation in this CRADA.

AUTHORITY: CRADAs are authorized by the Federal Technology Transfer Act of 1986, as amended and codified by 15 U.S.C. 3710a. DHS, as an executive agency under 5 U.S.C. 105, is a Federal agency for the purposes of 15 U.S.C. 3710a and may enter into CRADAs. DHS delegated the authority to conduct CRADAs to the Science and Technology Directorate and its laboratories.

Dated: January 21, 2016.

Kristin Wyckoff,Director,
Office of Public Private Partnerships.
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